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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/761,640	01/18/2001	Ming-Hui Wei	CL000964-CIP	6098

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EXAMINER	
NGUYEN, QUANG	

ART UNIT	PAPER NUMBER
1636	10

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/761,640	WEI ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2003 and 04 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,8,9 and 24-30* is/are pending in the application.

4a) Of the above claim(s) *26,28 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,8,9,24,25,27 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election without traverse of Group III (claims 4-5, 8-11 and 22-23) in Paper No. 7, and SEQ ID NO.1 which encodes SEQ ID NO:4 in Paper No. 9 is acknowledged.

Amended claims 4, 8-9 and 24-30 are pending in the present application.

Claim 26 is drawn to SEQ ID NO:23, while claims 28-29 are directed specifically to SEQ ID NO: 2, all of which are drawn to non-elected inventions (see Office Action in Paper No. 6, pages 4-5), and therefore they are withdrawn from further consideration.

Amended claims 4, 8-9, 24-25, 27 and 30 are examined on the merits herein.

Claim Objections

Claims 4, 8-9, 24, 27 and 30 are objected because they contain non-elected embodiments (SEQ ID NO:2 and SEQ ID NO:3).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 9 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

With respect to the elected invention, claim 9 is directed to a host cell containing the vector comprising a nucleic acid sequence of SEQ ID NO:1. Because Applicants intend to introduce the same expression vector into an animal including a human for

treatment purposes, the claim encompasses a transformed or transfected cell in a human. Since the claimed host cell is not recited as "isolated" or "cultured", the host cell containing the vector of the present invention reads on a transformed or transfected cell that is part of a human, which is a non-statutory subject matter.

Claims 4, 8-9, 24, 27 and 30 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either an asserted utility which is specific and substantial, or a well established utility for the same reasons set forth in the previous Office Action.

With respect to the elected invention, it is drawn to an isolated nucleic acid molecule encoding a phosphatase protein consisting of the nucleotide sequence of SEQ ID NO:1 which encodes SEQ ID NO:4; a vector and a host cell comprising the same nucleic acid molecule; an isolated nucleic acid molecule consisting of a nucleotide sequence that is completely complementary to SEQ ID NO:1; and a method for producing a polypeptide by culturing the same host cell.

When read in light of the instant specification, the claimed isolated nucleic acid molecule encodes a novel human MAP kinase phosphatase, which is based on the analysis of the sequence information of the human genome with previously unidentified fragments of the human genome that encode peptides that share structural and/or sequence homology to protein/peptide/domain identified and characterized within the art as being a phosphatase protein or part of a phosphatase protein and are related to the MAP kinase phosphatase subfamily (see instant specification, page 7, first full

paragraph). At the effective filing date of the present application, SEQ ID NO:1 is a novel nucleic acid sequence in the art, and therefore it has no well-established utility. Apart from disclosing SEQ ID NO:1 and stating that the sequence is detected in humans in the pancreas, colon, and pancreas adenocarcinomas, pancreas epithliod carcinoma, lung large cell carcinomas, renal cell carcinomas, placenta choriocarcinomas, ovary tumor tissue, brain (including fetal), heart (including fetal), kidney (including fetal), uterus, and thyroid, there is no evidence in the prior art at the effective filing date of the present application or from the instant disclosure that the protein encoded by SEQ ID NO:1 is actually expressed in nature, and that it possesses MAP kinase phosphatase activity. The protein encoded by SEQ ID NO:1 has 92% sequence identity to a hypothetical protein and 37% protein sequence identity to a *Drosophila* MAP kinase phosphatase (see Fig. 2, page 3). The sequence search does not reveal any significant homology between SEQ ID NO:1 with any sequence encoding for any member of the mammalian MAP kinase phosphatase family, including members such as MKP-1, VHR, PAC-1, MKP-2, B23/hVH-3, hVH-5, rVH-6/MKP-3 (Scimeca et al., Oncogene 15:717-725, 1997).

Apart from the concerns whether the protein encoded by SEQ ID NO:1 exists in nature and/or whether it actually functions as a physiological MAP kinase phosphatase, nothing was known on its role or its relative contribution to the inactivation of MAP kinases, which MAP kinases it inactivates, much less in which specific cellular processes *in vivo*? Nor is there any evidence of record indicating that there is a specific correlation between the expression of SEQ ID NO:1 or its encoded protein product with

any diseases or disorders. Therefore, on the basis of the instant disclosure, the significance and the physiological role of SEQ ID NO:1 and/or its encoded protein product is uncertain (e.g., **not specific**) and they remain to be established (e.g., **not substantial**). Accordingly, at the effective filing date of the present application, without further investigation or characterization of the nucleic acid molecule of SEQ ID NO:1 identified by the present invention, it is uncertain and unclear its physiological significance or role, and therefore the invention has no utility which is **specific** and **substantial**.

Furthermore, please note that it is well known in the art that sequence similarity does not reliably correlate to structural similarity and that structural similarity does not reliably result in similar and identical biological activities. For example, it is well known that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in may instances, albeit not in all cases. In the absence of factual evidence characterizing the structural and functional components of the biomolecule, the effects of these changes are largely unpredictable as to which ones will have a significant effect and which ones will be silent mutations having no effect. Several publications document the unpredictability of the relationship between sequence, structure, and function, although it is acknowledged that certain specific sequences have been found to be conserved in biomolecules having related function following a significant amount of further research. See Attwood (Science, 290:471-473, 2000); Gerhold et al. (BioEssays 18:973-981, 1996); Wells et al. (J. Leukocyte Biology 61:545-

550, 1997); Russell et al. (J. Mol. Biol. 244:332-350, 1994); and Kyrpides et al. (Mol. Microbiology 32:881-891, 1999). However, this level of factual evidence is absent here.

The specification asserts a variety of utilities for the claimed invention, including uses for diagnosis, prevention and treatment of biological processes associated with abnormal or unwanted protein phosphorylation, for identifying compounds that modulate phosphatase nucleic acid expression as well as compounds useful for treatment purposes, for identifying other family members or related sequences, for raising antibodies. However, such uses require the confirmation or evidence indicating that SEQ ID NO:1 is indeed encodes for a MAP kinase phosphatase existing in nature and/or its expression is correlated or associated with a specific disease or disorder. In the absence of such guidance provided by the instant specification, they do not constitute a **specific** and **substantial** utility at the effective filing date of the present application. A substantial utility is a utility that defines a "real-world" use. Utilities which require further research to identify or confirm a real-world use are not substantial utilities. For the reasons set forth above, a skilled artisan would not be able to use a nucleic acid molecule of SEQ ID NO:1 for any substantial purpose without further research or experimentation.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 8-9, 24, 27 and 30 are rejected under 35 U.S.C. 112, first paragraph. Because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility for the reasons set forth above under 35 U.S.C. 101, one skilled in the art would not know how to use the claimed invention at the effective filing date of the present application.

Conclusions

The prior art does not teach or fairly suggest a nucleic acid molecule of SEQ ID NO:1, a vector or an isolated host cell comprising the same as well as a method for producing a polypeptide by culturing the same isolated host cell.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Gerald Leffers, Jr., Ph.D., may be reached at (703) 305-6232, or SPE, Remy Yucel, Ph.D., at (703) 305-1998.

Quang Nguyen, Ph.D.

PATENT EXAMINER